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10/785,237	02/24/2004	Yves Millou	1026-04	1050

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EXAMINER

YU, GINA C

ART UNIT	PAPER NUMBER
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1617

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/785,237

Applicant(s)

MILLOU ET AL.

Examiner

Gina C. Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

The instant claim is rejected under 35 U.S.C. § 112, first paragraph, because the enablement for methods of prevention of acne lacks support from the applicant's specification or prior art. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with this claim.

Evaluating enablement requires determining whether any undue experimentation is necessary for a skilled artisan to determine how to make and/or use the claimed invention. Factors to be considered in determining whether any necessary experimentation is "undue" include, but are not limited to: the breadth of the claims; the nature of the invention; the state of the prior art, the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. See In re Wands, 858 F.2d 731, 737, 8 U.S.P.Q. 2d 1400, 1404 (Fed. Cir. 1988).

The breadth of the claims: The breadth of the claim is not commensurate with the scope of the disclosure. The disclosure of the specification is limited to a method of

reducing the appearance of wrinkle on the skin, but there is no enabling disclosure for preventing the wrinkles.

The nature of the invention: The subject matter of claim 12 pertains to a prevention of natural phenomena that occurs to all population.

The state of the prior art: Examiner is not aware of any prior art which enables a prevention of formation of wrinkle on the skin by topical application of an active ingredient.

The level of one of ordinary skill: One of ordinary skill in the anti-aging cosmetic composition art would not find the disclosure of the specification enabling in wrinkles prevention.

Level of predictability in the art: There is lack of predictability in the cosmetic art because a skilled artisan cannot readily anticipate the efficacy of the claimed method, which pertains to preventing a skin condition that naturally occurs to all humans.

The amount of direction provided by the inventor: The specification provides no guidance or direction on how to practice the claimed invention.

The existence of working examples: The specification provides no working example of the claimed invention.

The quantity of experimentation needed to make or use the invention: The burden of enabling the prevention of a skin condition (i.e., the need for additional testing) would be greater than that of enabling a treatment due to the need to screen those humans susceptible to such conditions.

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In the instant case, the specification does not provide guidance as to how one skilled in the art would go about preventing those patients susceptible to wrinkle within the scope of the presently claimed invention. Nor is there any guidance provided as to a specific protocol to be utilized in order to prove the efficacy of the presently claimed method in preventing the skin conditions among the patients. The specification fails to enable "prevention", and undue experimentation is necessary to determine screening and testing protocols to demonstrate the efficacy of the presently claimed method for the prevention of wrinkles.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 8 requires that the composition of claim 1, which already contains the essential oil of *Helichrysum italicum*, further comprises "an agent that augments production of collagen I and VEGF". The only agent that the specification discloses as a collagen I and VEGF promoter, is the essential oil of claim 1. See p. 5, [0026]. The specification does not describe other active agents that augment the production of collagen I and VEGF, nor is there any teaching about further addition of such agents to the composition which already contains the *Helichrysum* essential oil.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 1 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 8 is vague and indefinite as applicants do not define the agent that augments production of collagen I and VEGF, other than the essential oil which is already present in the base claim, claim 1. Since claim 8 requires a further addition of the agent, the claim requires an agent other than the essential oil. Applicants define the essential oil of the flower parts of *Helichrysum italicum* as the effective agent that promote the production of collagen I and VEGF, but no other agent of that effect is disclosed in the specification.

The remaining claims are rejected as depending on the indefinite base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1-4, 8, and 11-13 are rejected under 35 U.S.C. 102(b) as anticipated by Amrita("Helichrysum italicum", 1999, XP002224497).

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The invention in present claim 1 is a composition comprising a "substantially" purified essential oil extracted from flower tops of *Helichrysum italicum*. The term "antiwrinkle" denotes the property of the composition which inherently present in the composition. Alternatively, the term is a preamble which denotes an intended future use of the composition, and does not render any structural limitation to the composition. Thus no patentable weight is given to this term. See MPEP § 2111.02. The term "cosmetic" also refers to the intended use and purpose of the composition, and is treated as a preamble.

The Amrita online disclosure indicates the essential oil of *Helichrysum italicum*, grown in high altitudes and dry, sunny spots in Mediterranean region, has been commercially available as of 1999. The reference teaches that the essential oil is distilled from the flower part. See instant claim 2. The reference also teaches that the essential oil is added to skin care products for skin-rejuvenating properties. See instant claim 8. The claimed methods of 11-13 are inherently practiced every time the prior art skin care products are used as intended.

Since the prior art *Helichrysum* essential oil is obtained from the same source as the presently claimed invention, the prior art essential oil inherently contains the same components as required by instant claim 4. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. See In re Best, at 1255, 433. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are

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the same, the applicant has the burden of showing that they are not." See In re Spada at 709, 1658.

Claim 1-4, 8, 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Tyler (US 5785972).

Tyler discloses a topical antiseptic composition comprising the distilled oil of *Helichrysum italicum* flower head. See col. 1, line 63 – col. 2, line 20; instant claims 1-3, 8. The claimed methods of claims 11-13 are inherently practiced every time the prior art composition is applied as intended.

Claim 4 is inherently met since the prior art teaches *Helichrysum italicum* essential oil from the same source as the claimed invention. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. See In re Best, at 1255, 433. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." See In re Spada at 709, 1658.

Claim 1-5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Spina (Derwent ACC. No. 1999-471299, English abstract of FR 2774585) as evidenced by Tyler (US 5785972) and FR 2774585.

Spina discloses a topical composition for scalp, which comprises *Helichrysum italicum* essential oil. See Abstract, Novelty; instant claims 1, 2, and 8. The abstract also teaches that the composition has anti-inflammatory, wound healing, and antiseptic

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effect, thus it is viewed that the *Helichrysum italicum* essential oil is same as the essential oil that is obtained from the flower part of the plant. See Tyler, col. col. 1, line 57 – col. 2, line 15, which teaches that that *Helichrysum italicum* essential oil obtained from the flower head has antiseptic, anti-inflammatory, and wound healing properties. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. See *In re Best*, at 1255, 433. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." See *In re Spada* at 709, 1658.

With respect to claim 5, the French patent indicates that 1.1-1.3 g of *Helichrysum italicum* essential oil is used in 30 g of total preparation, which is equivalent to 3.7-4.3 wt %. See '585, p. 1, line 21; p. 2, component 3; instant claim 5. The full translation of the French document will be made available and cited in the next Office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spina (English abstract) in view of Tyler and FR 2774585 as applied to claims 1-5 and 8 as above.

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According to the French patent '585, the weight range of the *Helichrysum italicum* essential oil in the Spina composition is greater than the required amount of the instant claim.

Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this case the prior art amount of the *Helichrysum italicum* essential oil is close to the presently claimed amount, and the reference also provides the weight amounts of each component which makes up the total composition. It is viewed that the claimed amount is an obvious variation of the prior art, as one of ordinary skill in the art would have discovered an optimal weight amount of the essential oil by routine experimentations.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amrita as applied to claims 1-4, 8, and 11-13 as above, and further in view of Afirat et al. (US2002/0119954 A1).

Amrita does not teach the nanospheres formulation of instant claim 7 or the additives of instant claim 8.

Afirat teaches cosmetic composition comprising ascorbic acid, and also teaches that moisturizing active agents, in case of incompatibility with other materials, are incorporated into nanospheres in order to isolate them from each other in the

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composition. See p. 3-4, [0061]. Essential oils and vitamin E are taught. See instant claim 8.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to modify the teaching of Amrita by incorporating *Helichrysum italicum* essential oil and/or vitamin E into nanospheres, as motivated by Afriat, because both inventions of Amrita and Afriat are in cosmetic art, and Afriat teaches that it is well known in cosmetic art to incorporate essential oils or vitamin E moisturizing agent in nanospheres for stability of the composition and separation of the active ingredients during the storage. The skilled artisan would have had a reasonable expectation of successfully producing a stable composition comprising *Helichrysum italicum* in nanospheres.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605. The examiner can normally be reached on Monday through Friday, from 8:00AM until 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Gina C. Yu
Patent Examiner